Remarks

The Office Action mailed 9 September 2004 has been received and reviewed. The pending claims are claims 1-43 and 54-63. Reconsideration and withdrawal of the rejections are respectfully requested.

Interview Summary Record

Applicants wish to thank Examiners Choi and Clardy for the courtesy extended in the telephonic interview on December 7, 2004, with Applicants' Representative, Ann Mueting, and Inventor, Matthew Scholz. During the interview, it was explained that it was unexpected that lactic acid and an iodophor could be combined in a composition with a film-forming polymer at such high levels (particularly of lactic acid) without significant irritation. Applicants also discussed the ranges explicitly disclosed in Kross for the amount of lactic acid and the amount of iodophor and the disclosure in Kross regarding IGEPAL CO-720. Applicants presented arguments similar to those presented herein below. The possibility of presenting comparative results was also discussed and the Examiners indicated that they would be considered even though submitted in response to this Final Office Action.

Applicants' Invention

Claims 1-38, 41, 42, 43, and 54-63 of the present application relate to an antiseptic composition. The antiseptic composition includes an antimicrobial agent selected from I_2, an iodophor, and a combination thereof, a hydrocarboxylic acid buffer, water, and a substantive film-forming polymer. "Substantive" as it applies to a film-forming polymer means that when the film-forming polymer is applied to human skin as a uniform wet film and dried, it resists removal under certain conditions as defined on page 6, line 32 through page 7, line 9 of the specification.

Claim 39 of the present application relates to an antiseptic composition. The antiseptic composition includes an antimicrobial agent selected from I_2, an iodophor, and a combination thereof in an amount sufficient to provide an available iodine concentration of at least about 0.25

wt-%, a hydroxycarboxylic acid buffer, water, and a film-forming polymer comprising hydrophilic and hydrophobic moieties.

Obviousness-Type Double Patenting Rejection

Claims 1-21, 25-30, 33, 34, 37-39, 41-43, and 54-63 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 16-25, 27, 29-44, 47-60 of co-pending Application No. 10/052,158 in view of Kross et al. (U.S. Patent No. 5,618,841), Brink et al. (U.S. Patent No. 5,173,291), and Beach (U.S. Patent No. 3,380,923). Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-21, 25-30, 33, 34, 37-39, 41-43, and 54-63 under 35 U.S.C. §103(a) as being unpatentable over Kross et al. (U.S. Patent No. 5,618,841) in view of Brink et al. (U.S. Patent No. 5,173,291) and Beach (U.S. Patent No. 3,380,923). This rejection is respectfully traversed.

U.S. Patent No. 5,618,841 (Kross) discloses a composition for improving the anti-microbial activity of mammalian iodophor teat dips. The composition includes an iodophor and a specific organic acid buffer (column 2, lines 43-55). The composition may also include certain polymeric materials (column 5, lines 42-53). These polymers are not all necessarily substantive in the above-described meaning or comprise hydrophilic and hydrophobic moieties. These are significant features of the class of film-forming polymers used in Applicant's invention. Furthermore, even if there are substantive film-forming polymers or film-forming polymers that comprise hydrophilic and hydrophobic moieties within the classes of film-forming polymers disclosed in Kross, there is no teaching or suggestion in Kross that such polymers could be selected and combined with the other components in the recited amounts in Applicant's claims to

form an antiseptic composition. For this reason the subject-matter of instant claims is novel in view of Kross.

Furthermore, the compositions of Kross comprise a specific organic acid buffer. Although Kross mentions that, theoretically, concentrations of the organic acid buffer of from about 0.05% to 5.0% can be used, a concentration range of from 0.1% to 3.0% is given as being typical, while the preferred range is from 0.2% to 2% (column 5, lines 29-32). Moreover, the concentration of the organic buffers employed in the Examples ranges from 0.25% to 1.42% (column 6, line 15 to column 7, line 35). Since the instant claims require that the hydroxycarboxylic acid buffer is present in an amount of at least about 5 wt-% (e.g., claim 1), the only possible point of overlap is the edge value of 5 wt-%, which is mentioned as a theoretical upper limit in Kross. However, such high amounts of buffer are never used in Kross and the preferred range of Kross (from 0.2% to 2%) is far removed from this one point of possible overlap. The higher level of buffer used in the present application is particularly desirable in the iodophor-containing antiseptic compositions, in particular because the level of rapid microbial kill increases significantly with the concentrations of the hydroxycarboxylic acid (present application, page 13, lines 23-27).

Surprisingly, Applicants have found that the presently claimed compositions comprising a hydroxycarboxylic acid buffer in an amount of at least about 5 wt-% (and particularly in excess of 5 wt-%) in combination with an iodophor and a substantive film forming polymer are substantially nonirritating to tissue. This finding is particularly surprising in view of the fact that previous reports had indicated that high levels of alpha-hydroxy acids at an acidic pH can be irritating to the skin (present application, page 13, lines 9-22). See also the accompanying document (*Poucher's Perfumes, Cosmetics and Soaps*; 10th Edition; Butler, Ed.; Kluwer Academic Publishers; London; 2000) at page 436, which states:

> The most effective α-hydroxy acids tend to be lactic and glycolic and are used at 1-5% in mass products. Higher levels (up to 15%) can be used under the supervision of a dermatologist or trained beauty therapist. Alpha-hydroxy

acids can often cause irritation because of their low pH and are supplied as buffered solutions of pH 4.5.

Moreover, high concentrations of hydroxycarboxylic acid buffers would be expected to contribute to poor PSA-coated product adhesion and significantly reduced substantivity, since hydrophilic compounds facilitate moisture build-up from transpiration and perspiration in combination with external fluid exposure, resulting in premature adhesion failure (present application, page 15, lines 16-26). Surprisingly, Applicants found that, with certain hydroxycarboxylic acid buffers, concentrations of at least about 5 wt-% (and particularly in excess of 5 wt-%) in combination with the substantive film forming polymers still allow sufficient PSA-coated product adhesion and good substantivity. Hence, the combination claimed in the present application provides surprising advantages.

Furthermore, with respect to claim 29, for example, the Examiner indicates that Kross discloses surfactants. Although the Examples all refer to IGEPAL CO-720, which is nonylphenol ethoxylate with 12 moles of ethylene oxide (also referred to as nonylphenoxy polyoxy-ethanol, N=12), this polyether glycol forms an iodophor with iodine (see column 3, lines 28-32). That is, it is believed that any IGEPAL CO-720 added would complex with the iodine. There is no teaching or suggestion of a separate surfactant in the compositions of Kross.

U.S. Patent No. 5,173,291 (Brink et al.) does not provide that which is missing from Kross. It discloses the use of citric acid in a buffer solution in Examples 27-48. Examples 45 and 47-48 disclose the use of 5 grams of the buffer solution. The buffer solution is described at column 13, lines 27-32 (29.25 mLs of a 0.1M citric acid monohydrate solution and 70.75 mLs of a 0.20M disodium phosphate solution). This equates to a very small amount (less than 0.1 wt-%) of a hydroxycarboxylic acid. There is no teaching or suggestion of a composition with the high amount of hydroxycarboxylic acid buffer, as recited in Applicants' claims. In fact, the compositions of Brink et al. are dispersions which are salt intolerant and unstable, as discussed in the Declaration of Matthew T. Scholz presented herein.

It is not possible to repeat the examples of U.S. Pat. No. 4,173,291 (Kross) exactly since

nowhere in the Kross patent is the composition of the "iodophor concentrate" fully disclosed. Specifically, the concentration of the carrier polymer, nonylphenoxy polyoxyethanol (N=12) (IGEPAL CO-720), is not disclosed unless, of course, that the "20% iodophor concentrate" is simply a solution of iodine and iodide without carrier, and the carrier concentration is the nonylphenoxy polyoxyethanol, N=12 polymer that is disclosed in the table at the bottom of col. 3. This is not clear from reading Kross.

For this reason, after discussion with the Examiner, Example 27 of Brink et al. was repeated and the results presented in the accompanying Declaration of Matthew T. Scholz. The buffer was of a type and at a level to reflect the Kross invention (Paragraph 4 of Declaration of Matthew T. Scholz: Example with 2% lactic acid buffer). The concentration was increased further to reflect Applicants' invention (Paragraph 5 in Declaration of Matthew T. Scholz: Example with 5% lactic acid buffer), even though a fair reading of Kross is that he never intended to use more than 2% acid and that 5% was an extreme upper end. The lactic acid was used in place of the citric acid buffer of Example 27 since lactic acid was the acid used by Kross in the highest amount in the Examples. Note that the pH of the buffer was adjusted to between 5-7 in order to be within the preferred range of Brink (see Col. 8 line 59). This was done with disodium phosphate as was done in the original Example 27 of Brink.

Referring to the Declaration of Matthew T. Scholz it is very clear that one would not use a composition of Brink et al. and add a buffer of the type and level described in Kross. If one did, the composition would be highly unstable and form a coagulated mass, as shown in the declaration of Matthew T. Scholz.

U.S. Patent No. 3,380,923 (Beach) does not provide that which is missing from Kross or Brink et al. In fact, there is no teaching or suggestion of compositions that include hydroxycarboxylic acids in Beach. Thus, there is no motivation to combine this document with either of the others.

It is respectfully submitted that there is no teaching or suggestion in the prior art of Applicants' invention. Specifically, there is no teaching or suggestion of how to provide

antiseptics having increased speed of bactericidal activity on skin without substantial irritation while still allowing adhesion of PSA-coated products and good substantivity. There is no indication to be found in the combination of Kross, Brink et al., and Beach that this problem can be solved by providing one of the antiseptic compositions of the present invention that contain, among other components, a hydroxycarboxylic acid buffer in an amount of at least about 5 wt-% (and particularly in excess of 5 wt-%).

Summary

It is respectfully submitted that the pending claims 1-43, and 54-63 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
Matthew T. SCHOLZ et al.
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
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January 10, 2005
Date

By: Ann M. Mueting
Ann M. Mueting
Reg. No. 33,977
Direct Dial (612) 305-1217

CERTIFICATE UNDER 37 CFR §1.10:
"Express Mail" mailing label number: EV 201 891 162 US Date of Deposit: 10 January 2005
I hereby certify that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Rachel Oglinski-Graham
Name: Rachel Oglinski-Graham

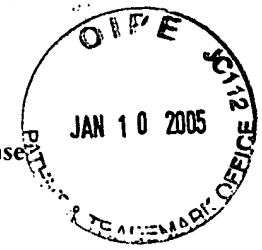


Exhibit A

Amendments to the Specification

Please replace the paragraph beginning at page 17, line 21, with the following amended paragraph.

Examples of suitable hydrophobic and hydrophilic monomers are described in Applicants' Assignee's copending U.S. Patent Application Serial No. [_____]10/052,158, filed on ~~even date herewith~~ January 16, 2002, entitled FILM-FORMING COMPOSITIONS AND METHODS ~~Attorney Docket No. 57339 US002~~, and published as U.S. Patent Publication No. 2003-0194415 A1.

Please replace the paragraph beginning at page 18, line 3, with the following amended paragraph.

Preferred film-forming polymers are cationic polymers, particularly those that include side-chain functional amine groups. Examples of such groups include protonated tertiary amines, quaternary amines, amine oxides, and combinations thereof. Preferred such polymers are described in Applicants' Assignee's copending U.S. Patent Application Serial No. [_____]10/052,158, filed on ~~even date herewith~~ January 16, 2002, entitled FILM-FORMING COMPOSITIONS AND METHODS ~~Attorney Docket No. 57339US002~~,and published as U.S. Patent Publication No. 2003-0194415 A1.

PATENT
Docket No. 57338US002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Matthew T. SCHOLZ et al.	Group Art Unit:	1616
Serial No.:	10/051,719	Examiner:	Frank I. Choi
Confirmation No.:	8633		
Filed:	16 January 2002		
For:	ANTISEPTIC COMPOSITIONS AND METHODS		

DECLARATION OF MATTHEW T. SCHOLZ

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Matthew T. Scholz, declare and say as follows:

1. I am a co-inventor of the subject matter claimed in the above-identified U.S. Patent Application Serial No. 10/051,719, filed January 16, 2002.

2. I have read the Office Action mailed on September 9, 2004, and the documents cited therein, and make the following Declaration in support of the patentability of the claims.

3. Example 27 of U.S. Pat. No. 5,618,841 (Brink et al.) begins with preparation of an acrylic dispersion in Example 2. This was prepared according to the procedure set forth in Example 2. To 17.39 g of this dispersion was added 13.57 g deionized water in a 4 oz jar. To this was added 0.4 g of a buffer dropwise with good stirring on a stir plate. The buffer was prepared in accordance with Example 27 and is detailed below:

Buffer Preparation

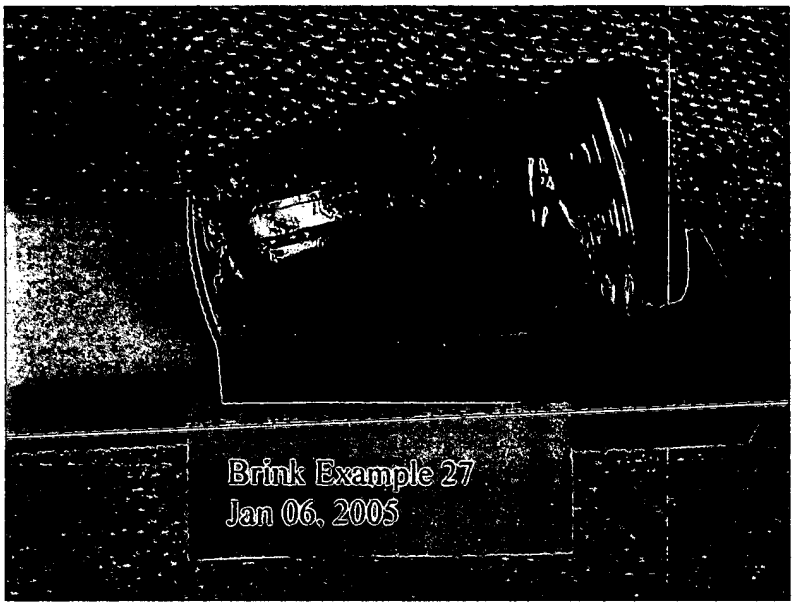
0.1M Citric acid (Aldrich Lot 05724JI) solution was prepared in deionized water

0.2M Disodium phosphate was prepared from disodium phosphate heptahydrate (Mallikrodt lot 7914KJMH) in deionized water

To 29.25 ml 0.1M citric acid solution was added 70.75 ml 0.2M disodium phosphate solution.

The pH of this buffer solution was measured and found to be 6.58.

Potassium iodide solutions were added slowly as laid out in Example 27. First, 3.4 g of a KI premix prepared by dissolving 0.4 g KI (Mallinkrodt) in 3 g deionized water was added in 1ml increments approximately every 30 min. The solution had to be warmed to keep the KI in solution. The solution was added slowly at each addition point. Next, 5.2 g of a KI premix made by dissolving 0.2 g KI in 5 g deionized water was added in 1ml increments added approximately every 30 min. Once this addition was complete the solution was stirred 60 min and allowed to sit overnight. The next morning 0.4 g iodine crystals (Aldrich DF0923LZ) were added by adding 0.1 g iodine every 30 min. The solution turned brown. A lot of iodine remained undissolved. The dispersion was stirred overnight and the iodine had dissolved by morning. The dispersion was stirred a total of 24 hours and then allowed to sit for 2 hours. A uniform brown dispersion was produced with very little coagulation. The dispersion was low in viscosity and flowed freely. A photo of the composition is shown below:

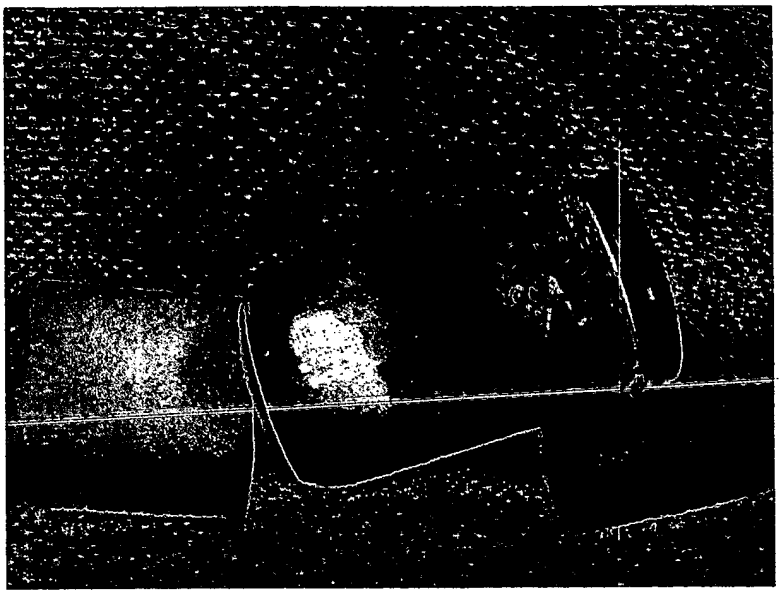


After sitting for greater than 24 hours there was no change in the appearance of this dispersion. It appeared to be stable.

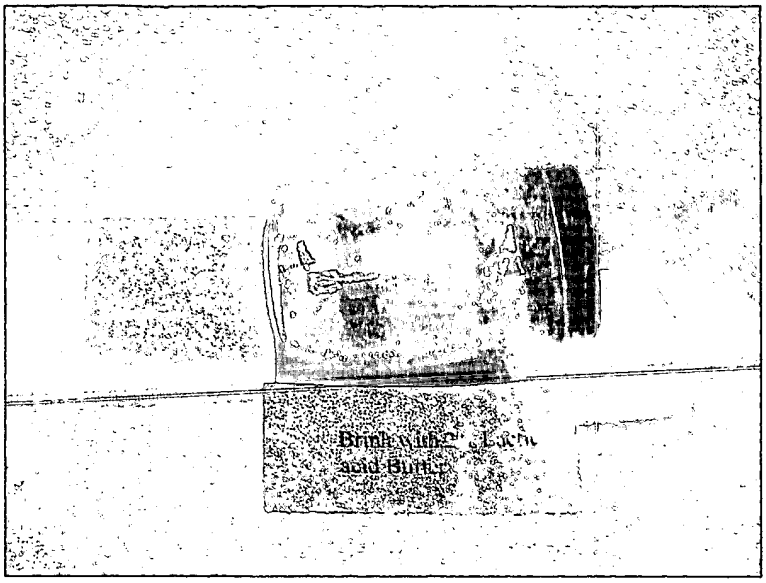
4. Buffer preparation:

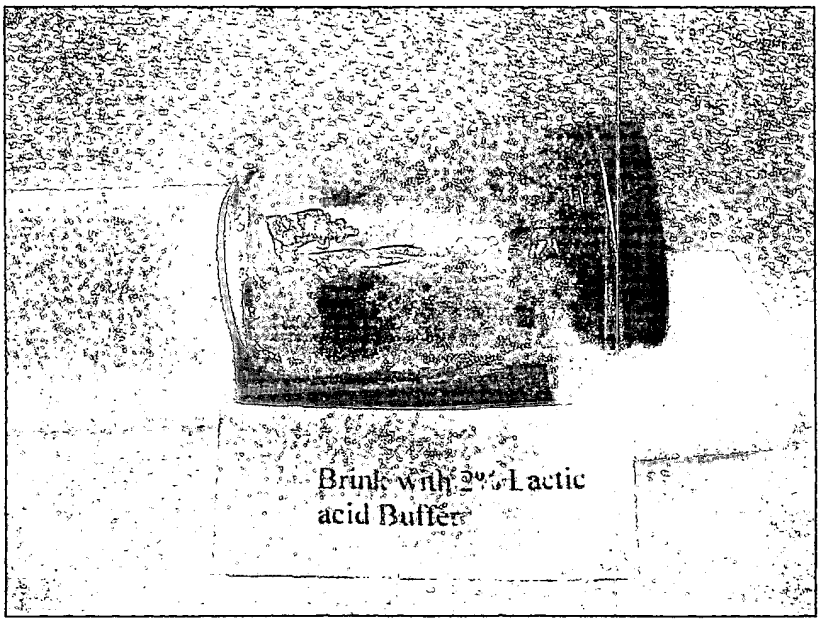
0.90 g 90% lactic acid (Purac) was added to 4.44 g water and 2.66 g disodium phosphate heptahydrate. This was mixed and warmed to dissolve the contents. The pH was measured and found to be 5.80.

To 17.39 g of the Example 2 dispersion was added 5.57 g deionized water in a 4 oz jar. To this was added 8.4 g of the above lactic acid/phosphate buffer. The buffer was added in 1 g increments every 30 min. At each addition the 1g was added dropwise with good stirring on a stir plate. After addition of 2 g of the buffer solution some coagulation was already evident with small agglomerates appearing on the sides of the jar. After 3 g were added a photo was taken and this is shown below.



The remainder of the buffer solution was added 1 g every 30 min until the entire 8.4 g was added. By this time a large portion of the polymer appeared to be coagulated. The dispersion was stirred overnight. The next morning, potassium iodide solutions were added slowly as laid out in Example 27. First, 3.4 g of a KI premix prepared by dissolving 0.4 g KI in 3 g deionized water was added in 1ml increments approximately every 30 min. The solution had to be warmed to keep the KI in solution. The solution was added slowly at each addition point. Next, 5.2 g of a KI premix made by dissolving 0.2 g KI in 5 g deionized water was added in 1 ml increments added approximately every 30 min. Once this addition was complete the solution was stirred 60 min. The next morning 0.4 g iodine crystals were added by adding 0.1 g iodine every 30 min. The solution turned brown. A lot of iodine remained undissolved. The dispersion was stirred overnight and the iodine had dissolved by morning. The dispersion was stirred a total of 24 hours and then allowed to sit for 2 hours. A completely coagulated mass resulted with a small amount of clear brown liquid adjacent to the mass. A photo of the composition is shown below:

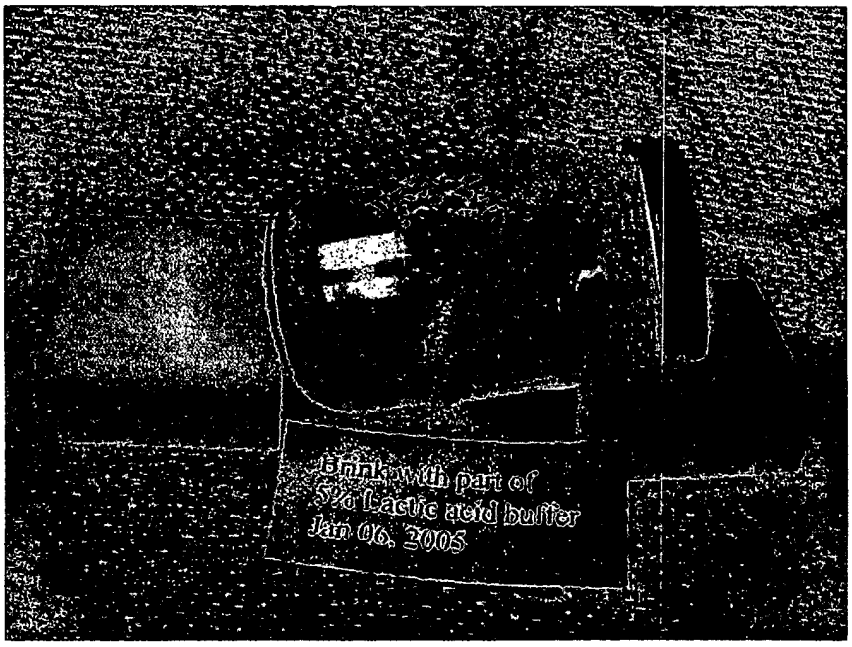


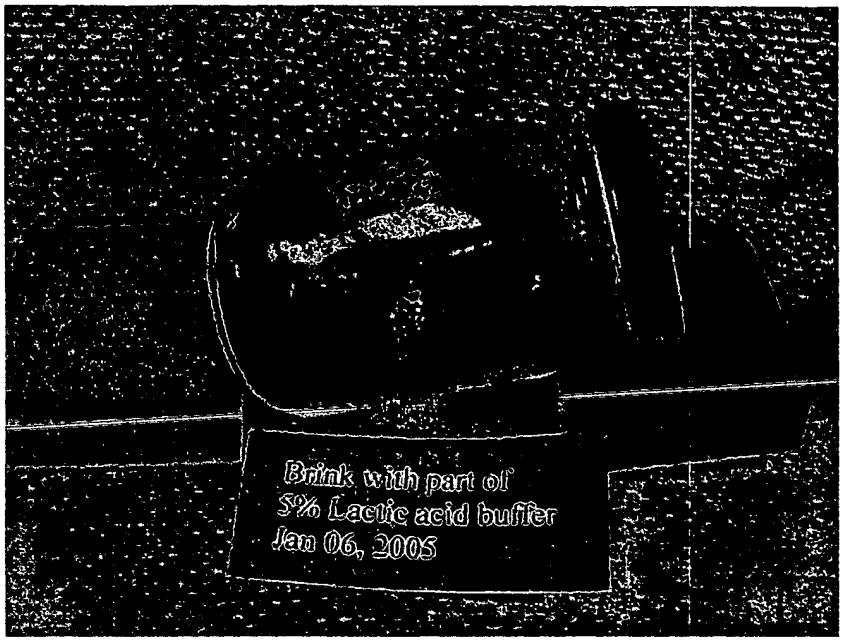


5. Buffer preparation:

2.24 g 90% lactic acid (Purac) was added to 5.10 g water and 6.66 g disodium phosphate heptahydrate. This was mixed and warmed to dissolve the contents. The pH was measured and found to be 5.64.

To 17.39 g of the Example 2 dispersion was added the above lactic acid/phosphate buffer. The buffer was added in 1g increments every 30 min. At each addition the 1 g was added dropwise with good stirring on a stir plate. After addition of 2 g of the buffer solution some coagulation was already evident with small agglomerates appearing on the sides of the jar. After only 6 g of the 14 g of buffer were added most of the polymer had coagulated out of solution and agglomerated onto the stir bar to the point that the stir bar would not stir. Nor could the contents be stirred after the stir bar was removed from the mass. The mass was elastomeric and could not be broken up with a spatula. The experiment was aborted. A photo was taken and this is shown below.





After sitting overnight the entire contents gelled to a solid white mass.

6. I further declare that statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Matthew T. Scholz
Name

1-10-05
Date

Exhibit B

PATENT
Docket No.57338US002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Matthew T. SCHOLZ et al.	Group Art Unit:	1616
Serial No.:	10/051,719	Examiner:	Frank I. Choi
Confirmation No.:	8633		
Filed:	16 January 2002		
For:	ANTISEPTIC COMPOSITIONS AND METHODS		

COMMUNICATION RE: NOTICE OF NON-COMPLIANT AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

In response to the Notice of Non-Compliant Amendment, Applicants submit herewith a replacement page entitled "Amendments to the Specification," which replaces page 2 of the Amendment and Response originally filed on 3 March 2004. Applicants have marked the paragraphs with underlining to show insertions and strikethrough to show deletions. The amendments to the specification update the application serial number, filing date, and publication number in a cited application. As noted in the Notice of Non-Compliant Amendment and pursuant to 37 C.F.R. §1.121(h), "Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be resubmitted." Therefore, Applicants believe the Amendment and Response originally filed on 3 March 2004 is now complete.

The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23rd day of June, 2004, at 9:04 a.m. (Central Time).

Signature: Rachel England-Gilson
Name: Rachel England-Gilson

June 23, 2004
Date

Respectfully submitted for

Matthew T. SCHOLZ et al.

By
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By: Ann M. Mueting
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AMM/rgg

Auto-Reply Facsimile Transmission

Exhibit C

TO: Fax Sender at 6123051228

Fax Information
Date Received: 6/23/2004 10:05:09 AM [Eastern Daylight Time]
Total Pages: 4 (including cover page)

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Received Cover Page =======>

06/23/2004 09:04 FAX 6123051228 MUETING RAASCH GEBHARDT 0001

PATENT
Docket No.57338US002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Matthew T. SCHOLZ et al.
Serial No.: 10/051,719
Confirmation No.: 8633
Filed: 16 January 2002
For: ANTISEPTIC COMPOSITIONS AND METHODS

Group Art Unit: 1616
Examiner: Frank I. Choi

FACSIMILE TRANSMISSION TO THE PTO

Mail Stop Amendment
Commissioner for Patents
Attn: Examiner Frank I. Choi
P.O. Box 1450
Alexandria, VA 22313-1450

FAX NUMBER: (703) 872-9306
Total Pages (including cover page): 4 pgs.
Time: 9:04 a.m. (Central Time)
(Transmission must be complete by midnight eastern time.)

The following papers are being transmitted to the Patent and Trademark Office by facsimile transmission: Communication Re: Notice of Non-Compliant Amendment (2 pgs); replacement page 2 for Amendment and Response filed on 3 March 2004 entitled "Amendments to the Specification" (1 pg).

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895.

June 23, 2004
Date

Mueting, Raasch & Gebhardt, P.A.
By: Ann M. Mueting
Ann M. Mueting
Reg. No. 33,977
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CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Facsimile Cover Sheet and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office addressed to the Commissioner for Patents, Attn: Examiner Frank I. Choi, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23rd day of June, 2004, at 9:04 a.m. (Central Time).

June 23, 2004
Date

Signature:
Name: Rachel Coglianese-Gabera

If you do not receive all pages, please contact us at (612)305-1220 (ph) or (612)305-1228 (fax).

PAGE 1/1 * RCVD AT 6/23/2004 10:05:09 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/1 * DNIS:2729306 * CSID:6123051228 * DURATION (mm-ss):01-22